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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	10/726,110
Filing Date	December 2, 2003
First Named Inventor	Gary Searle
Art Unit	3731
Examiner Name	Webb, Sarah K
Attorney Docket Number	03-062-GS

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
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  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

Corrected Appeal Brief in Response to Notification of Non-Compliant Appeal Brief (37 CFR 41.37)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Lambert and Associates		
Signature	Adam J Bruno		
Printed name	Adam J. Bruno		
Date	5/7/2007	Reg. No.	58,390

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Adam J Bruno		
Typed or printed name	Adam J. Bruno	Date	5/9/2007

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 10/726,110	Applicant(s) SEARLE, GARY
	Examiner NGUYEN, ANH-TUAN	Art Unit 3731

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *26 February 2007* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

Item 10. A signature is needed for the Appeal Brief filed February 26, 2007.

Lorenda Hood

LORENDA HOOD
PATENT APPEAL CENTER SPECIALIST

Appl. No.	:	10/726,110
Applicant	:	Gary Searle
Filed	:	December 2, 2003
TC/A.U.	:	3731
Examiner	:	WEBB, SARAH K
Docket No.	:	03-062-GS

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CORRECTED APPEAL BRIEF

Sir or Madam:

Please find enclosed an Appeal Brief in support of the above-referenced application.

REAL PARTY IN INTEREST

The real party in interest is Mr. Gary Searle, as inventor and applicant.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-105 have been finally rejected. Claims 2, 8, 15, 24-75 and 78-105 have been withdrawn. Claims 1, 3-7, 9-14, 16-23, 76 and 77 are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1

Claim 1 defines a device comprising cylindrical stent body having opposing ends with a body wall having a surface extending therebetween and an expandable filler material uniformly bonded to a thin sheet rolled upon itself having a circumference extending around a longitudinal stent axis and including a barrier film for encapsulating said stent. **(Detailed Description of the Invention, pg. 18, lines 21-23 through pg. 19, lines 1-9)**

Claim 3

Claim 3 defines a stent as described in claim 1 wherein the stent body is manufactured from ELGILOY. **(Detailed Description of the Invention, pg. 19, lines 10-14)**

Claim 4

Claim 4 defines a stent as described in claim 1 wherein the expandable filler material is soluble. **(Detailed Description of the Invention, pg. 20, lines 4-6)**

Claim 5

Claim 5 defines a stent as described in claim 1 wherein the expandable filler material is inert. **(Detailed Description of the Invention, pg. 20, lines 4-6)**

Claim 6

Claim 6 defines a stent as described in claim 1 wherein the expandable filler material utilized is casein. **(Detailed Description of the Invention, pg. 18, line 21)**

Claim 7

Claim 7 defines a stent as described in claim 1 wherein the barrier film is manufactured from polypropylene. **(Detailed Description of the Invention, pg. 20, lines 11-12)**

Claim 9

Claim 9 defines a stent as described in claim 1 wherein the barrier film is porous. **(Detailed Description of the Invention, pg. 20, lines 11-12)**

Claim 10

Claim 10 defines a stent as described in claim 1 wherein the expandable filler material is pressure formed onto the thin sheet. **(Detailed Description of the Invention, pg. 19, lines 16-17)**

Claim 11

Claim 11 defines a stent as described in claim 1 wherein the stent is crimped onto a catheter. **(Detailed Description of the Invention, pg. 21, lines 3-4)**

Claim 12

Claim 12 defines a stent as described in claim 1 wherein a catheter is used for implantation. **(Summary of the Invention, pg. 4, lines 9-10)**

Claim 13

Claim 13 defines a stent as described in claim 1 wherein the barrier film is hermetically heat sealed. **(Detailed Description of the Invention, pg. 20, lines 12-14)**

Claim 14

Claim 14 defines a stent as described in claim 1 wherein the stent, the expandable filler material, the thin sheet, and the barrier film are biocompatible. **(Detailed Description of the Invention, pg. 20, lines 4-6)**

Claim 16

Claim 16 defines a stent as in claim 1 wherein an angioplasty balloon is used for implantation. **(Detailed Description of the Invention, pg. 18, lines 21-23)**

Claim 17

Claim 17 defines a stent as described in claim 1 wherein a thromboresistant coating is applied to the barrier film. **(Summary of the Invention, pg. 9, lines 17-19)**

Claim 18

Claim 18 defines a stent as described in claim 1 wherein heparin is applied to the barrier film. **(Detailed Description of the Invention, pg. 9, lines 17-19)**

Claim 19

Claim 19 defines a stent as described in claim 1 wherein the stent is used in conjunction with another stent. **(Summary of the Invention, pg. 14, lines 11-13; Summary of the Invention, pg. 15, lines 3-5)**

Claim 20

Claim 20 defines a stent as described in claim 1 wherein said stent is utilized in procedures pertaining to animals. **(Detailed Description of the Invention, pg. 23, lines 11-13)**

Claim 21

Claim 21 defines a stent as described in claim 1 wherein the stent is utilized in procedures pertaining to humans. **(Summary of the Invention, pg. 4, lines 7-8)**

Claim 22

Claim 22 defines a stent as described in claim 1 wherein the thin sheet is foil. **(Detailed Description of the Invention, pg. 18, lines 21-23 through pg. 19, line 1)**

Claim 23

Claim 23 defines a stent as described in claim 1 wherein the thin sheet is polymeric. **(Summary of the Invention, pg. 9, lines 4-9)**

Claim 76

Claim 76 defines an apparatus for dilating or occluding a vessel comprising a mechanical element that conforms to a cylindrical shape whose natural or unrestrained state is slightly larger than the intended inner diameter of the vessel following dilation, the element is restrained to a smaller diameter to allow placement to the target site using a percutaneous catheteral procedure, in the constrained state, the element exerts an outward force that, if unrestrained, would allow the element to expand to the natural state, the element is restrained mechanically by means of materials whose properties change over time due to exposure to blood protein, serum, enzymes, or changes in pH, these materials dissolve, expand or undergo changes in their physical properties to allow the element to expand slowly to the natural state. **(Summary of the Invention, pg. 12, lines 4-8; Detailed Description of the Invention, pg. 19, lines 5-9)**

Claim 77

Claim 77 defines an apparatus as described in claim 77 wherein said mechanical element is a thin sheet rolled upon itself that is introducible to the inside of a vessel having expanded and contracted conditions, wherein in the contracted condition the thin sheet is in a multiple layer roll having a tendency to radially expand and having a smaller diameter extending around a longitudinal axis, said sheet radially expands having a larger diameter extending around said longitudinal axis in said expanded condition. **(Detailed Description of the Invention, pg. 5, lines 20-24; Detailed Description of the Invention, pg. 18, lines 21-23 through pg. 19, line 1)**

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claim Rejections – 35 USC §102

The Examiner rejected claims 76 and 77 under 35 USC §102 as being anticipated by U.S. Patent No. 6,517,575 issued to Yang et al.

According to the Examiner, Yang discloses a self-expanding stent that is in the form of a rolled sheet. The rolled sheet has many layers, including a layer of expandable filler material. Yang explains that the expandable filler material swells upon absorbing water when placed in a body lumen (column 2, lines 45-50 and column 4, lines 60-65).

Claim Rejections – 35 USC §103

The Examiner rejected claims 1, 4, 5, 9-14, 16, and 19-23 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,458,152 issued to Khosravi et al. in view of Yang.

According to the Examiner, Khosravi discloses a rolled sheet self-expanding stent that includes layers of different materials. One layer, or "stent body," is formed from a shape memory metal (column 6, lines 40-45). A polymeric layer is disposed on the interior of the stent body and can be in the form of several layers (column 3, lines 35-45). An additional polymer layer can be disposed on the exterior of the stent to form a "barrier film," and it can be porous (column 5, lines 35-50). An alternate barrier film encapsulating the stent it disclosed (column 7, line 61 through column 8, line 5). The stent can also include a coating of heparin (column 8m lines 63-65). A balloon catheter can be used for implantation (column 9, line 36 and Figure 5B).

According to the Examiner, Khosravi fails to include an expandable filler material, but does state that the inner polymer layer can be formed as several layers (column 3, lines 35-45). Khosravi also requires a balloon catheter for aiding in the expansion of the prosthesis. As explained above, Yang also discloses a rolled sheet self-expanding vascular prosthesis. Yang teaches that this type of prosthesis should include an expandable filler material bonded to another thin sheet. The expandable material aids in the self-expansion of the stent, as it causes the sheet to unroll and expand as the material swells when in contact with water in the body lumen. Yang also explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3). These statements provide motivation to combine the Yang and Khosravi devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the multilayered polymer portion of the Khosravi stent as an expandable filler material bonded to a thin sheet, as Yang teaches that this combination of materials aids in the self expansion of a rolled sheet stent. The expanding material may be capable of replacing the use of a balloon catheter.

According to the Examiner, Yang also states that the expandable layer may be biodegradable and gives many examples of materials that can form the expandable polymer layer in column 3. The expandable layer (20) is disposed on a thin sheet of material that can be polymeric or metallic (10) (column 2, lines 55-60). Yang explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3).

Also according to the Examiner, claims 10 and 13 only include limitations pertaining to the method by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious and is not governed by whether the process by which it is made is patentable. Therefore, the limitations of claims 10 and 13 were not given patentable weight.

The Examiner further asserts, claims 19-21 only pertain to the intended use of the device. The only requirement here is that the prior art stent be capable of performing these functions. Since the Yang stent is capable of being used with another stent and in procedures pertaining to animals or humans, it meets the limitations of claims 19-21.

Claim Rejections – 35 USC §103

The Examiner rejected claim 3 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,042,605 issued to Martin et al.

According to the Examiner, the modified Khosravi device fails to form the stent body from a cobalt-chrome alloy or Elgiloy. Khosravi does state that the stent body can be formed of nitinol or stainless steel (column 6, lines 41-45). Martin discloses a stent body disposed over a

polymer graft. Martin teaches that Elgiloy is a suitable material to use as a substitute for nitinol, as it is highly resilient (column 11, lines 5-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Elgiloy for nitinol for the material of the stent body of the modified Khosravi stent, as Martin teaches that Elgiloy has good mechanical properties for forming stents.

Claim Rejections – 35 USC §103

The Examiner rejected claim 6 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,428,571 issued to Lentz et al.

According to the Examiner, as explained above, Yang discloses many different materials for forming the expandable layer in column 7. Among those materials are gelatin, collagen, albumin, and starch. Lentz teaches that casein is another natural material equivalent to gelatin, collagen, albumin, and starch for forming expandable polymer layers (column 8, lines 38-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include casein in the expandable filler material of the modified Khosravi device, as Lentz teaches that casein in simply an alternate natural material for forming expandable polymer layers.

Claim Rejections – 35 USC §103

The Examiner rejected claim 7 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 5,824,046 issued to Smith et al.

According to the Examiner, Khosravi states that the outer polymer layer, or "barrier film," can be formed of graft materials, such as PTFE, polyester, or urethane (column 7, lines 11 and 64). Smith discloses a stent with a polymeric outer layer. Smith teaches that polypropylene

is a suitable substitute for PTFE, polyurethane, and polyester for forming the barrier film (column 7, lines 32-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier film of the modified Khosravi device of polypropylene, as Smith teaches that this material is suitable for forming a barrier film for a stent.

ARGUMENT

Claim Rejections – 35 USC §102

The Examiner rejected claims 76 and 77 under 35 USC §102 as being anticipated by U.S. Patent No. 6,517,575 issued to Yang et al.

According to the Examiner, Yang discloses a self-expanding stent that is in the form of a rolled sheet. The rolled sheet has many layers, including a layer of expandable filler material. Yang explains that the expandable filler material swells upon absorbing water when placed in a body lumen (column 2, lines 45-50 and column 4, lines 60-65). The limitation "unrestrained state is slightly larger than the intended inner diameter of the vessel" is considered to be very broad, since vessels are known to have various diameters.

RESPONSE

The Yang patent cited by the Examiner was issued for Multilayer Liquid Absorption and Deformation Devices. As discussed below, the present invention differs from the Yang patent in several respects.

In Yang, the purpose of the water absorbing material 12 is for deployment only (column 1, lines 63 through column 2, line 14 and Figure 4). In contrast, the device of the present

invention is partially deployed by use of a balloon, and additional expansion of the stent occurs as fluid is absorbed from the bloodstream over time (page 4, lines 12-13).

The Yang patent states that the invention "is analogous in a general way to a bimetal" (column 1, lines 53-54). In a bimetal structure each layer expands differently so as to deform the combined structure. Therefore, all that occurs with the Yang device is deformation or expansion of the structure, not occlusion of the vessel.

"A previous patent . . . anticipates a purported invention only where, except for insubstantial differences, it contains all of the same elements operating in the same fashion to perform an identical function." *National Business Systems, Inc. v. Am International, Inc.*, 743 F.2d 1227, 1235 (7th Cir. 1984) (quoting *Popeil Bros., Inc. v. Schick Electric, Inc.*, 494 F.2d 162, 164 (7th Cir. 1974)). As discussed, the Yang patent does not operate in the same fashion as the present invention to perform an identical function.

The materials identified in the Yang patent would be classified as hydrophilic (column 2, lines 50-57). The absorbable materials that are identified in the application for the present invention are not listed in the Yang patent, i.e. casein and superabsorbers. The moisture absorption of the Yang hydrophilic materials is far less than casein or a superabsorber. As a result, the Yang hydrophilic materials could not be used for occlusion, only deployment. It should be noted that the benefits to the patient from slow deployment are not discussed.

The Yang device includes two components that could be combined with a stent (column 1, line 63 through column 2, line 14). The absorbable material of the device of the present invention is completely different and with different characteristics than those described of the Yang patent. The absorbable material in the device of the present invention is then combined with a stent. All three components of the device of the present invention are then encapsulated in

a barrier material, which is used to control the rate of occlusion. The Yang device could not be used for occlusion, regardless of the amount of absorbable material that was used, because the materials do not expand as does casein or a superabsorber.

Further, in the device of the present invention, the absorbable material is bonded to a thin foil. The main purpose of the foil is to inhibit the absorbable material from expanding into the openings of the stent. The foil slides across the open surface of the stent, expanding the stent and occluding the vessel. If the absorbable material could enter the openings in the stent, (a) expansion of the stent could be irregular, non-cylindrical, or (b) portions of the absorbable material could break away, or (c) plaque could be dislodged from the vessel, or (d) the vessel could be damaged.

Moreover, and the following analysis applies for all claims rejected in light of Yang in any manner, the structure of the instant device wholly differs from that of Yang as the instant invention possesses differing layers and components, and said components each have different functions than those claimed and described in the specification of Yang.

Yang's claims (1, 3, and 11) describe how the device will "shrink", due to water absorption. Despite the fact that such tendency does imply vaso-dilation, conversely and not accidentally, as indicated by the specification of the instant invention, one novel feature of the instant invention exists as follows: as water is absorbed into the device alternatives, thus the outer diameter will either grow or remain the same while the inner diameter reduces. An apparent difference to one of skill in the art exists since, in Yang's device the outer layer absorbs the fluid; and whereas, in the instant device(s) the inner layer absorbs the fluid. Therefore, regardless of the existence of some common components, the Yang device and the instant device

are entirely different in nature, as additionally illustrated by the differing metallic (non-absorbing) layer illustrated in the instant invention as compared to that of Yang's.

Further, an existing product the Ameroid Constrictor (AC), which is produced by Research Instruments, Inc. is a vaso-occlusion device used in the veterinary industry and is the predicate device that inspired the instant invention. As illustrated by literature, the photograph attached as Exhibit 1 and photographs listed on the website (http://www.proaxis.com/~kpm/) for Research Instruments as of July 13, 2006, the AC is a bi-layer device, the outer layer being rigid (stainless steel), and the inner layer being water absorbable (casein) and highly expandable. The C-shaped structure allows the AC to be deployed around a portosystemic shunt during soft tissue surgery. Once in place, a cross-pin or dowel is used to restrain the AC from migrating away from the target site.

As shown in the photos, the AC on the left is shown without the cross-pin and the view on the right is of a larger AC with the cross-pin in place. Also of note, the thickness of the stainless steel outer band (the shiny portion of the device) can be estimated at 0.040 to 0.060 inches thick. The grayish, thicker inner ring is composed of casein. The behavior of this two-layer structure is unlike a bimetal structure, unlike Yang's structure, and also unlike the instant structure, thus illustrating the numerous behavioral patterns existing within what appear to be closely related structures. The outer layer of the AC is sufficiently thick to resist deformation possibly caused by absorption of water by the casein, i.e. the AC does not behave as a bimetal.

Therefore, due to the extended recovery time exhibited subsequent to soft tissue surgery, the focus of the instant invention relates to development of vaso-occlusion and dilation concepts which incorporate an expandable, metallic stent for structural integrity and still can be deployed

with commonly used methods, such as Percutaneous Coronary Interventions (previously called Angioplasty, Percutaneous Transluminal Coronary (PTCA), or Balloon Angioplasty).

Thus, for the above reasons and for those that follow, the instant invention cannot be thought of as a natural progression of Yang's invention, since Yang's device is not intended to occlude or dilate. The materials the Yang device do not mimic the performance of the material combination(s) defined in the instant invention as only minimal absorption and displacement of his selected polymer is possible or necessary for his device to perform as intended. Any wound tube composed of layered materials with differing degrees of absorption will behave similarly to Yang's stent, but none, including Yang's, will perform or function in the manner proposed by the instant invention. Therefore, blindly substituting the proposed material considerations outlined in the instant invention into Yang's design would not allow his device to function similarly.

The following is a list of physical differences in the bi-layer structures claimed in Yang's and the instant invention as follows:

1. In figure 2 of Yang's patent, two alternatives are shown for the bi-layer structure. In one alternative, the absorbing layer is on the outer diameter, and the second alternative shows the absorbing layer on the inner diameter. However, in all of Yang's **claims** the outer layer is always referred to as the absorbable layer, which in turn causes the bi-layer structure to bend or shrink as shown in the first alternative of figure 2;

2. The deformation of the non-absorbing layer in Yang's invention provides the intended function of the device or bi-layer structure, i.e. the bending or shrinking of the device. In the instant invention, the non-absorbing layer does not deform as the absorbing layer expands;

3. In the instant invention, the non-absorbing layer is rigid, and expansion of the absorbing layer increases the thickness of the bi-layer structure, i.e. the intent of expansion is to change the radial dimension of the cylindrical, bi-layer structure. The expansion of the bi-layer structure in Yang's invention is lateral or transverse to the non-absorbing layer, which results in bending or shrinking;

4. In the instant invention, the non-absorbing layer functions primarily as a scaffold to retain the absorbing material;

5. For all alternatives of instant invention, the rigid, non-absorbable layer is the outer layer. In all of Yang's **claims**, the non-absorbable layer is the inner layer;

6. In the instant invention, the bi-layer structure is located inside a stent, which is typically of mesh design, i.e. having a highly open surface area. The rigid, non-absorbing layer also protects the absorbing layer from fracture as the absorbing layer expands. If the rigid, non-absorbing layer were not on the outside of the absorbing layer, the absorbing layer would expand into and through the open area of the stent and either reduce or negate the intended function of the device, or the absorbing layer may separate into pieces;

7. Yang's bi-layer device is intended to function by itself. The instant device performs its intended function in combination with a stent and micro-porous barrier. The bi-layer structure in instant device couldn't perform the intended function without the other components, e.g. the pore density and pore size of the micro-porous barrier determine the occlusion or dilation duration;

8. Searle's bi-layer structure is placed inside a metallic stent and that assembly is encapsulated within a micro-porous barrier all of which comprises Searle's invention / device. The metallic stent provides the rigidity/integrity for the device, which otherwise would collapse in the blood vessel;

9. As stated in the patent, Yang's concept is based on bimetal behavior. The bi-layer structure in the instant invention is not intended to mimic bimetal behavior. The rigid, non-absorbable material acts (1) as a scaffold to retain the absorbable material, (2) to inhibit the absorbable material from penetrating the open area of the stent, as the absorbable material expands, and (3) allows the coiled, bi-layer structure to slide or uncoil freely as the absorbable material expands. These functions of the rigid, non-absorbable layer are not related to the functions of material used in a bimetal structure;

10. For a bi-metal structure (or Yang's structure) to behave as intended, the two layers must be intimately bonded, and due to differences in the expansion rates of the two materials the combined structure deflects. The device of the instant invention is not based on bimetal behavior, and would perform as intended if the two layers were not bonded, and only held in close proximity to each other, so that the non-absorbing layer could provide the functions noted in 3 above. Yang's device would not perform as intended if the two layers were not intimately boned; and,

11. Yang's device alternative, as described beginning in section 4, line 25, would require soft tissue surgery, and the instant invention would only require a catheteral procedure.

Further in line with the above series of differentiations, the fact that the Yang specification equates the invention to a bimetal structure should be considered. Neither layer in a bimetal structure requires a significant rate of expansion to achieve the intended function of the device, and the deflection of the structure is based on the differential expansion rates of the two

materials, as stated by the Yang patent. Also, Z-axis expansion or expansion of the thickness of the absorbable layer is not necessary for a bimetal structure to perform as intended. Thus, upon review of the figures of the fully expanded absorbable layer in both patents, the difference in behavior is obvious. The Yang cross-section shows no noticeable growth in the thickness of the absorbable layer, while the absorbable layer in the instant device completely occludes the inner diameter.

The Yang device cannot behave in that manner, as even if a super absorber was utilized, the Yang absorbable layer device would invert, i.e. the inner, absorbable layer would expand laterally to a degree that it would become the outer layer. However, in reality, usage of the Yang invention in this manner would in all likelihood cause patient injury. Additionally, excessive expansion of the absorbable layer might also cause delamination, resulting in a loss of intended function. The bi-layer structure found in the instant invention cannot invert, because it is housed within a metallic stent, and thus, if the absorbable layer delaminates, the device will still perform as intended, as all of the particles will be encapsulated by the micro-porous barrier.

Finally, the Examiner has rejected Applicant's arguments exhibiting that the references fail to show certain features of Applicant's invention because the missing elements are not recited in the rejected claim(s). However, this is not an accurate statement, and Applicant respectfully argues that the elements are recited within the claims. For example, Claim 76 recites in part that the natural state of the element, the "natural or unrestrained state is slightly larger than the intended inner diameter of the vessel." This shows that the element is not only intended to result in occlusion, but that the element is *structurally* capable of achieving occlusion because of the physical characteristics of the element, i.e. its structure. Therefore, Applicant reiterates the argument that the Yang invention is not capable of achieving the desired result of

Applicant's invention because the Yang invention does not disclose a structure capable of achieving the desired result. This fact serves as evidence that there exists significant differences in structure that would preclude a finding of anticipation based on 35 USC §102.

Moreover, this is not a case where Applicant is seeking to read limitations from the specification into the claims. With regard to the expandable materials recited in claim 76, the specification discloses what those materials actually comprise. If multiple materials were disclosed, some capable of occlusion and others that were not, the Examiner's assertion would have increased merit. However, as this is not the case, Applicant asserts that the claims recite elements that when read in light of the specification are disclosed with sufficient particularity so as to differentiate the materials from those disclosed by Yang.

Claim Rejections – 35 USC §103

The Examiner rejected claims 1, 4, 5, 9-14, 16, and 19-23 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,458,152 issued to Khosravi et al. in view of Yang.

According to the Examiner, Khosravi discloses a rolled sheet self-expanding stent that includes layers of different materials. One layer, or "stent body," is formed from a shape memory metal (column 6, lines 40-45). A polymeric layer is disposed on the interior of the stent body and can be in the form of several layers (column 3, lines 35-45). An additional polymer layer can be disposed on the exterior of the stent to form a "barrier film," and it can be porous (column 5, lines 35-50). An alternate barrier film encapsulating the stent it disclosed (column 7, line 61 through column 8, line 5). The stent can also include a coating of heparin (column 8m lines 63-65). A balloon catheter can be used for implantation (column 9, line 36 and Figure 5B).

Additionally, according to the Examiner, Khosravi fails to include an expandable filler material, but does state that the inner polymer layer can be formed as several layers (column 3, lines 35-45). Khosravi also requires a balloon catheter for aiding in the expansion of the prosthesis. As explained above, Yang also discloses a rolled sheet self-expanding vascular prosthesis. Yang teaches that this type of prosthesis should include an expandable filler material bonded to another thin sheet. The expandable material aids in the self-expansion of the stent, as it causes the sheet to unroll and expand as the material swells when in contact with water in the body lumen. Yang also explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3). These statements provide motivation to combine the Yang and Khosravi devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the multilayered polymer portion of the Khosravi stent as an expandable filler material bonded to a thin sheet, as Yang teaches that this combination of materials aids in the self expansion of a rolled sheet stent. The expanding material may be capable of replacing the use of a balloon catheter.

Furthermore, according to the Examiner, Yang also states that the expandable layer may be biodegradable and gives many examples of materials that can form the expandable polymer layer in column 3. The expandable layer (20) is disposed on a thin sheet of material that can be polymeric or metallic (10) (column 2, lines 55-60). Yang explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3).

Moreover, according to the Examiner, claims 10 and 13 only include limitations pertaining to the method by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious and is not governed by whether the process by

which it is made is patentable. Therefore, the limitations of claims 10 and 13 were not given patentable weight.

Finally, according to the Examiner, claims 19-21 only pertain to the intended use of the device. The only requirement here is that the prior art stent be capable of performing these functions. Since the Yang stent is capable of being used with another stent and in procedures pertaining to animals or humans, it meets the limitations of claims 19-21.

RESPONSE

The Khosravi patent cited by the Examiner was issued for a Coiled Sheet Graft for Single and Bifurcated Lumens and Methods of Making and Use. As discussed below, the present invention differs from the Khosravi patent in several respects.

The usage of the Khosravi device usage is different than the usage of the device of the present invention. A stent graft is used to repair damage, such as a hole, in an artery or major vessel. The "graft" material replaces the vessel wall, and the stent provides structural integrity for the graft. The examples offered in the patent include a hole in the artery caused by an aneurysm or a gunshot (column 3, line 15 and column 2, line 51).

The two-layered Khosravi device described includes a "graft" material to patch the hole, and a metal layer, the two being spirally wound (column 5, lines 27-29). The metal layer in Khosravi is functioning to provide structural integrity to the graft. In the device of the present invention, there is a separate stent, and the spirally wound element is the foil, with the primary purpose to inhibit the absorbable material from entering the openings of the stent during occlusion.

The metal used for the metal layer in Khosravi is a "shape-memory" alloy (column 3, line 49), which has been selected because it will expand partially, due to the "shape-memory"

properties. However, a mechanical expander is still required for complete deployment (claims 2 and 5, and Figure 5B). In fact, the Khosravi patent makes no reference to any absorbable materials.

The device of the present invention is completely deployed by a balloon or other mechanical means. The foil in the device of the present invention does not truly expand, but follows the expansion of the absorbable material that is attached to the foil. In addition, the arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

With respect to claims 10 and 13, Applicant has respectfully requested that claim 10 be included within Invention #2 and that claim 13 be included within Invention #4.

Claim Rejections – 35 USC §103

The Examiner rejected claim 3 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,042,605 issued to Martin et al.

According to the Examiner, the modified Khosravi device fails to form the stent body from a cobalt-chrome alloy or Elgiloy. Khosravi does state that the stent body can be formed of nitinol or stainless steel (column 6, lines 41-45). Martin discloses a stent body disposed over a polymer graft. Martin teaches that Elgiloy is a suitable material to use as a substitute for nitinol, as it is highly resilient (column 11, lines 5-40). It would have been obvious to one of ordinary

skill in the art at the time the invention was made to substitute Elgiloy for nitinol for the material of the stent body of the modified Khosravi stent, as Martin teaches that Elgiloy has good mechanical properties for forming stents.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Martin patent cited by the Examiner was issued for a Kink Resistant Stent-Graft. As discussed below, the present invention differs from the Martin patent in several respects.

Like Khosravi, the Martin device is also a stent graft. There are three components in the Martin device: a stent formed of thin wire, a graft material, and a material connecting the two, i.e. the helically wound "ribbon" (column 2, line 51). The graft material may be "any material which is suitable for use as a graft in the chosen body lumen" (column 12, lines 23-24). The ribbon is the only wound component, although the wire mesh of the stent does follow a helical pattern, and could also be considered as helically wound (column 9, line 67). However, wound

implies a manufacturing process, and although the final appearance of the mesh is helical, a weaving process is used instead of a winding process to produce it.

Further, the connecting ribbon of Martin is helically wound, and therefore the winds do not overlap each other. Instead, the winds are adjacent to each other with a space in between. The space is intentional and provides flexibility to the stent graft to facilitate deployment at the target site.

In contrast, the wound components in the device of the present invention are "spirally" wound to allow each layer of the wound assembly to slide freely over each other as the absorbable material expands to occlude the vessel (Figure 1(a) and 2(b)).

Claim Rejections – 35 USC §103

The Examiner rejected claim 6 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,428,571 issued to Lentz et al.

According to the Examiner, as explained above, Yang discloses many different materials for forming the expandable layer in column 7. Among those materials are gelatin, collagen, albumin, and starch. Lentz teaches that casein is another natural material equivalent to gelatin, collagen, albumin, and starch for forming expandable polymer layers (column 8, lines 38-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include casein in the expandable filler material of the modified Khosravi device, as Lentz teaches that casein in simply an alternate natural material for forming expandable polymer layers.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Lentz patent cited by the Examiner was issued for Self-Sealing PTFE Vascular Graft and Manufacturing Methods. As discussed below, the present invention differs from the Lentz patent in several respects.

The Lentz device is comprised of two layers, both of PTFE. One is more porous to allow natural tissue growth, and the other provides radial strength and resistance to axial tear (column 3, lines 4-7). The two distinct layers are actually extruded tubes of PTFE. The purpose of this invention is to support hemodialysis, which typically involves puncturing the graft to withdraw blood (column 6, lines 56-64). The need they have solved is to create a self-sealing graft.

Although one of the claims of the patent application of the present invention identified PTFE as a barrier material (withdrawn claim 8), polypropylene was selected as the barrier film of the elected embodiment (claim 7). In the device of the present invention, the barrier material completely encapsulates the stent and spirally wound components, and is used to control the rate of moisture absorption and thereby control the rate of occlusion. This is accomplished by

dictating the pore density and pore size of the barrier material. Lentz device is not encapsulated in a barrier material. Therefore, Lentz's use of PTFE is different than in the device of the present invention.

Claim Rejections – 35 USC §103

The Examiner rejected claim 7 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 5,824,046 issued to Smith et al.

According to the Examiner, Khosravi states that the outer polymer layer, or "barrier film," can be formed of graft materials, such as PTFE, polyester, or urethane (column 7, lines 11 and 64). Smith discloses a stent with a polymeric outer layer. Smith teaches that polypropylene is a suitable substitute for PTFE, polyurethane, and polyester for forming the barrier film (column 7, lines 32-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier film of the modified Khosravi device of polypropylene, as Smith teaches that this material is suitable for forming a barrier film for a stent.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Smith patent cited by the Examiner was issued for a Covered Stent. As discussed below, the present invention differs from the Smith patent in numerous respects.

The Smith invention utilizes a PTFE barrier material in combination with a stent (column 5, lines 20-22). However, the sole purpose of the barrier is to inhibit particles, such as plaque, on the wall of the vessel from traveling through the openings of the stent and causing blockage, restenosis, or other issues at the target site or elsewhere in the vascular system (column 1, lines 44-52). The barrier as defined is only on the outer surface of the stent, somewhat like a sleeve.

In the device of the present invention, the barrier completely encapsulates the stent and spirally wound components for the primary purpose of controlling the rate of moisture absorption and thereby controlling the rate of occlusion. This is accomplished by dictating the pore density and pore size of the barrier material. Additionally, the barrier of the present invention also acts to prevent bacteria ingress, since the size of bacteria is larger than the pore size used in the barrier.

Also, by encapsulating the entire device, any portion of the absorbable material that breaks away during deployment or expansion is captured and can not migrate in the bloodstream to cause a blockage elsewhere. In the device of the present invention, the preferred barrier is actually polypropelene (PP), because it is more hydrophilic than PTFE, and it can be heat-sealed. PTFE could be used in place of PP in the device of the present invention, but the PTFE

would need to be modified through radiation grafting or some other means to improve moisture absorption (hydrophilic tendency).

Finally, since Khosravi fails to include the expandable filler material, the combination of Yang and Khosravi will do nothing to correct the deficiencies noted above in the Yang disclosure. The same reasoning is also applicable to the additions of U.S. Patent No. 6,042,605 to Martin (hereinafter "Martin") and U.S. Patent No. 6,428,571 to Lentz, et al. (hereinafter "Lentz"). Thus since the combination of these patents to Yang will not render Applicant's invention obvious when Yang fails to disclose elements that are significantly different in structure and operation from that of Applicant.

Reconsideration and further examination is respectfully requested. The Commissioner is hereby authorized to charge any additional fees, which may be required for this amendment, or credit any overpayment to Deposit Account No. 12-0115.

Applicant has made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Gary E. Lambert, Applicant's Attorney at (617) 720-0091 so that such issues may be resolved as expeditiously as possible.

For these stated herein and in view of the above remarks and arguments, Applicant asserts that this application is now considered to be in condition for allowance and such action is earnestly solicited. Applicant respectfully contends that all rejected claims are patentable.

Therefore, reversal of all rejections is courteously solicited.

Respectfully Submitted,

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CLAIMS APPENDIX

1. A stent comprising:

a generally cylindrical stent body having proximal and distal opposing ends with a body wall having a surface extending therebetween;

an expandable filler material uniformly bonded to a thin sheet rolled upon itself having a circumference extending around a longitudinal stent axis; and

a barrier film for encapsulating said stent.

2. (withdrawn) A stent as in claim 1 wherein:

the stent is manufactured from stainless steel.

3. (amended) A stent as in claim 1 wherein:

the stent body is manufactured from ELGILOY.

4. A stent as in claim 1 wherein:

the expandable filler material is soluble.

5. A stent as in claim 1 wherein:

the expandable filler material is inert.

6. A stent as in claim 1 wherein:

the expandable filler material utilized is casein.

7. A stent as in claim 1 wherein:

the barrier film is manufactured from polypropylene.

8. (withdrawn) A stent as in claim 1 wherein:

the barrier film is manufactured from polytetraflouroethylene.

9. A stent as in claim 1 wherein:

the barrier film is porous.

10. A stent as in claim 1 wherein:

the expandable filler material is pressure formed to the thin sheet.

11. A stent as in claim 1 wherein:

the stent is crimped onto a catheter.

12. A stent as in claim 1 wherein:

a catheter is used for implantation.

13. A stent as in claim 1 wherein:

the barrier film is hermetically heat sealed.

14. A stent as in claim 1 wherein:

the stent, the expandable filler material, the thin sheet, and the barrier film are biocompatible.

15. (withdrawn) A stent as in claim 1 wherein the expandable filler material utilized can be chosen from the group of superabsorbent polymers consisting of sodium polyacrylate and polyacrylamide.

16. (amended) A stent as in claim 1 wherein:

an angioplasty balloon is used for implantation.

17. A stent as in claim 1 wherein:

a thromboresistant coating is applied to the barrier film.

18. A stent as in claim 1 wherein:

heparin is applied to the barrier film.

19. A stent device as in claim 1 wherein:

the stent is used in conjunction with another stent.

20. A stent device as in claim 1 wherein:

said stent is utilized in procedures pertaining to animals.

21. A stent device as in claim 1 wherein:

said stent is utilized in procedures pertaining to humans.

22. A stent device as in claim 1 wherein:

the thin sheet is foil.

23. A stent device as in claim 1 wherein:

the thin sheet is polymeric.

24. (withdrawn) A method for bonding the expandable filler material to the thin sheet according to claim 1 comprising:

unrolling the thin sheet through an embossing roll;

depositing the expandable filler material from a bulk feeder onto the thin sheet;

spreading with a doctor blade the expandable filler material uniformly on the thin sheet;

pressure bonding the expandable filler material and the thin sheet with a calendar rolls.

25. (withdrawn) A method for longitudinally rolling the expandable filler material and the thin sheet and insertion into the stent according to claim 1 comprising:

cutting the bonded thin sheet and expandable filler material to the length and circumference of the stent;

rolling longitudinally the bonded sheet and the expandable filler material; and

inserting the bonded sheet and the expandable filler material into the stent.

26. (withdrawn) A method for hermetically heat sealing the barrier film according to claim 11 comprising:

cutting the barrier film to the appropriate length;

folding the barrier film around the stent;

welding ultrasonically a U-shaped seam into the barrier film;

inserting the expandable filler material bonded to the thin sheet into the folded barrier film;

welding ultrasonically the barrier film and the expandable filler material bonded to the thin sheet on the U-shaped seam; and

folding the top of the U-shaped seam into the stent.

27. (withdrawn) A detachable balloon comprising:

a balloon capable of assuming deflated and inflated states having at least one opening;

a crimp ring surrounding the outside circumference of the balloon opening;

a septum surrounding the inside circumference of the balloon opening covering the balloon opening; and

a rigid band surrounding the inside circumference of the septum.

28. (withdrawn) A detachable balloon as in claim 27 wherein:

said balloon is disposed in and secured to a generally cylindrical stent body having proximal and distal opposing ends with a body wall having a surface extending therebetween.

29. (withdrawn) A detachable balloon as in claim 28 wherein:

heparin is applied to the outside of the stent.

30. (withdrawn) A detachable balloon as in claim 28 wherein:

a thromboresistant coating is applied to the outside of the stent.

31. (withdrawn) A detachable balloon as in claim 27 wherein:

a plurality of attaching bands secure said balloon to said stent.

32. (withdrawn) A detachable balloon as in claim 27 wherein:

an expandable filler material inflates said balloon.

33. (withdrawn) A detachable balloon as in claim 27 wherein:

the expandable filler material is a solution of saline and expandable particles.

34. (withdrawn) A detachable balloon as in claim 27 wherein:

the expandable filler material is polyvinyl alcohol.

35. (withdrawn) A detachable balloon as in claim 27 wherein:

the expandable filler material is gelatin foam.

36. (withdrawn) A detachable balloon as in claim 27 wherein:

the expandable filler material is n-butyl-cyanoacrylate.

37. (withdrawn) A detachable balloon as in claim 27 wherein:

the expandable filler material is a gas.

38. (withdrawn) A detachable balloon as in claim 27 wherein:

a diaphragm and a convex core ring seals said balloon.

39. (withdrawn) A detachable balloon device as in claim 38 wherein:

a syringe and a plunger is used for deflation.

40. (withdrawn) A detachable balloon as in claim 38 wherein:

a syringe is used for deflation.

41. (withdrawn) A detachable balloon as in claim 27 wherein:

a catheter is used for implantation.

42. (withdrawn) A detachable balloon as in claim 27 wherein:

a syringe is used for inflation.

43. (withdrawn) A detachable balloon as in claim 27 wherein:

a syringe is used for deflation.

44. (withdrawn) A detachable balloon as in claim 27 wherein:

a syringe and a plunger is used for inflation.

45. (withdrawn) A detachable balloon as in claim 27 wherein:

heparin is applied to the outside of the balloon.

46. (withdrawn) A detachable balloon as in claim 27 wherein:

a thromboresistant material is applied to the outside of the balloon.

47. (withdrawn) A detachable balloon as in claim 27 wherein:

the balloon is latex.

48. (withdrawn) A detachable balloon as in claim 27 wherein:

the balloon is silicon.

49. (withdrawn) A detachable balloon as in claim 27 wherein:

the balloon is polypropylene.

50. (withdrawn) A detachable balloon as in claim 27 wherein:

the balloon is polytetraflouroethylene.

51. (withdrawn) A detachable balloon as in claim 27 wherein:

the rigid band is stainless steel.

52. (withdrawn) A detachable balloon as in claim 27 wherein:

the rigid band is egiloy.

53. (withdrawn) An internal ligation device comprising:

a housing;

at least one sharp each of said sharps having a pointed tip located at the proximal end and distal opposing end with a sleeve having a surface extending therebetween wherein the said proximal end is unattached wherein the distal end is placed inside of the housing;

at least one slide each of said slides having a proximal end and a distal end wherein the proximal end is unattached and wherein the distal end is placed inside of the sharps;

at least one cutting blade each of said cutting blades having a proximal end and a distal end wherein the proximal end is unattached and wherein the distal end is placed inside of the housing;

at least one suture, each of said sutures having a proximal end and distal end wherein the proximal end is folded over said slide and wherein the distal end is placed inside of the housing.

54. (withdrawn) An internal ligation device as in claim 53 wherein:

a clamping mechanism is located above said sutures.

55. (withdrawn) An internal ligation device as in claim 53 wherein:

a means for cauterization is used to sever the excess of the sutures.

56. (withdrawn) An internal ligation device as in claim 53 wherein:

a plurality of plungers are used to control the internal ligation device.

57. (withdrawn) An internal ligation device as in claim 53 wherein:

the sharps are stainless steel.

58. (withdrawn) An internal ligation device as in claim 53 wherein:

the cutting blades are stainless steel.

59. (withdrawn) An internal ligation device as in claim 53 wherein:

the housing is stainless steel.

60. (withdrawn) An internal ligation device as in claim 53 wherein:

the clamping mechanism is polypropylene.

61. (withdrawn) An internal ligation device as in claim 53 wherein:

the sharp sleeves are polypropylene.

62. (withdrawn) An internal ligation device as in claim 53 wherein:

the slides are polypropylene.

63. (withdrawn) An internal ligation device as in claim 53 wherein:

the sharp sleeves are preformed in a curved shape.

64. (withdrawn) An internal ligation device as in claim 53 wherein:

the sutures are monofiliament.

65. (withdrawn) An internal ligation device as in claim 53 wherein:

the sutures are braided.

66. (withdrawn) An internal ligation device as in claim 53 wherein:

a catheter is used for implantation.

67. (withdrawn) An internal ligation device as in claim 53 wherein:

there are 3 slides.

68. (withdrawn) An internal ligation device as in claim 53 wherein:

there are 3 sharps.

69. (withdrawn) An internal ligation device as in claim 53 wherein:

there are 3 sutures.

70. (withdrawn) An internal ligation device as in claim 53 wherein:

there are 3 cutting blades.

71. (withdrawn) A method for ligating a vessel comprising the steps of:

placing an internal ligation device within a vessel by percutaneous catheteral procedure;

advancing a plurality of sharp sleeves;

advancing a plurality of slides;

piercing the vessel wall with a plurality of sharps;

advancing the slides;

expanding a plurality of preformed sutures outside of the vessel wall;

retracting the slides to suture release surfaces;

shedding the sutures;

retracting the slides and the sharp sleeves inside the internal ligation device; and

tightening the sutures.

72. (withdrawn) The method of claim 71 further comprising:

advancing the cutting blades wherein the sutures are severed on the top surface of the clamps.

73. (withdrawn) The method of claim 71 further comprising:

cauterizing the sutures wherein the sutures are severed on the top surface of the clamps.

74. (withdrawn) The method of claim 71 further comprising:

cauterizing the sutures bonding them together.

75. (withdrawn) The method of claim 71 wherein:

plungers are used in order to control the internal ligation device.

76. An apparatus for dilating or occluding a vessel, the apparatus comprising:

a mechanical element that conforms to a cylindrical shape whose natural or unrestrained state is slightly larger than the intended inner diameter of the vessel following dilation, the element is restrained to a smaller diameter to allow placement to the target site using a percutaneous catheteral procedure, in the constrained state, the element exerts an outward force that, if unrestrained, would allow the element to expand to the natural state, the element is restrained mechanically by means of materials whose properties change over time due to exposure to blood protein, serum, enzymes, or changes in pH, these materials dissolve, expand or undergo changes in their physical properties to allow the element to expand slowly to the natural state.

77. The apparatus of claim 76 wherein:

said mechanical element is a thin sheet rolled upon itself that is introducible to the inside of a vessel having expanded and contracted conditions, wherein in the contracted condition the thin sheet is in a multiple layer roll having a tendency to radially expand and having a smaller diameter extending around a longitudinal axis, said sheet radially expands having a larger diameter extending around said longitudinal axis in said expanded condition.

78. (withdrawn) The apparatus of claim 77 further comprising:

at least one ring surrounds the outside of the thin sheet constraining the thin sheet in the contracted condition wherein said ring restrains the thin sheet from expanding radially.

79. (withdrawn) The apparatus of claim 78 further comprising:

a porous barrier film controlling the ingress of fluid for encapsulating said thin sheet and said ring.

80. (withdrawn) The apparatus of claim 79 further comprising:

a generally cylindrical stent body having proximal and distal opposing ends with a body wall having a surface extending therebetween wherein said ring surrounds said stent and said stent encompasses said thin sheet.

81. (withdrawn) The apparatus of claim 80 further comprising:

an expandable filler material uniformly bonded to the thin sheet wherein exposure to liquid expands the expandable filler material occluding the larger diameter of the thin sheet in said expanded condition.

82. (withdrawn) The apparatus of claim 81 wherein:

said expandable filler material is comprised of superabsorbent polymer.

83. (withdrawn) The apparatus of claim 81 wherein:

said expandable filler material is comprised of hygroscopic polymer.

84. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material of which the mechanical properties diminish over time from exposure to a bloodstream.

85. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material of which the mechanical properties diminish over time from exposure to a blood protein.

86. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material of which the mechanical properties diminish over time from exposure to blood serum.

87. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material of which the mechanical properties diminish over time from exposure to enzymes.

88. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material of which the mechanical properties diminish over time from exposure to a change in pH.

89. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that dissolves over time from exposure to the bloodstream.

90. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that dissolves over time from exposure to a blood protein.

91. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that dissolves over time from exposure to blood serum.

92. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that dissolves over time from exposure to enzymes.

93. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that dissolves over time from exposure to a change of pH.

94. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that expands over time from exposure to the bloodstream.

95. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that expands over time from exposure to a blood protein.

96. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that expands over time from exposure to blood serum.

97. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that expands over time from exposure to enzymes.

98. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a material that expands over time from exposure to a change of pH.

99. (withdrawn) The apparatus of claim 78 wherein:

said ring is comprised of a polymer having tensile strength in which the tensile strength attenuates with moisture absorption.

100. (withdrawn) An apparatus for dilating a vessel, the apparatus comprising:

a sintered or porous tube wherein a first portion of said tube is closed and of reduced diameter such that the reduced diameter can be disposed inside of a channel of a second portion of said tube that is introducible to the inside of a vessel; and

an expandable filler material disposed inside of the channel of the second portion of the tube wherein exposure to liquid expands the expandable filler material forcing the first

portion out of said channel abutting the tube to the inside of a vessel, thus expanding the vessel.

101. (withdrawn) The apparatus of claim 100 wherein:

said sintered sheet is comprised of porous material.

102. (withdrawn) The apparatus of claim 100 wherein:

said expandable filler material is comprised of superabsorbent polymer.

103. (withdrawn) An apparatus for dilating a vessel comprising:

a thin sheet that is introducible to the inside of a vessel having an interior surface and an exterior surface, a plurality of cavities disposed on the interior surface and the exterior surface, the thin sheet having expanded and contracted conditions, wherein in the contracted condition, the thin sheet is in a multiple layer roll having a tendency to radially expand and having a smaller diameter extending around a longitudinal axis wherein the cavities disposed on the interior surface are coupled with the cavities disposed on the exterior surface in an aligned configuration forming a plurality of enclosed pockets, wherein in said expanded condition said sheet radially expands having a larger diameter extending around said longitudinal axis wherein the cavities disposed on the interior surface and exterior surface are in a misaligned configuration; and

at least one key disposed in said enclosed pockets wherein said key restrains said tube in the contracted condition and exposure to liquid dissolves said key.

104. (withdrawn) The apparatus of claim 103 wherein:

said key is comprised of material that dissolves.

105. (withdrawn) The apparatus of claim 103 wherein:

a plurality of keys have increasing dimensions allowing sequential expansion of the device.

EVIDENCE APPENDIX

The following is the evidence submitted by the examiner and relied upon by appellant in the appeal.

6,517,575	Yang
6,458,152	Khosravi
6,042,605	Martin
5, 824,046	Smith

RELATED PROCEEDINGS APPENDIX

There are no decisions rendered by a court or the Board in any proceeding as noted in the section titled: RELATED APPEALS AND INTERFERENCES.